As stated in 80-81 BEC 2, the Assurance of Compliance with Department of Health and Human Services Regulations on Protection of Human Subjects, the Chair of the Institutional Review Board (IRB) shall report annually to the AVP of the Office of Research and Sponsored Programs, and through the Chair of the Committee on Research to the Chair of the Academic Senate.

80-81 BEC 2 states that the annual report must contain six elements:

1) **The dates of all IRB meetings and the attendance.**

Most human subjects research conducted at CSUEB is of minimal risk and is evaluated via expedited review, which is coordinated via campus mail and email. No full board meetings were required this year.

2) **The total number of projects and activities reviewed, including statistics on expedited reviews, approvals, rejections, and deferred protocols.**

<table>
<thead>
<tr>
<th>Type of Review</th>
<th>Faculty/Staff-Initiated</th>
<th>Student-Initiated</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Board</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Expedited Review</td>
<td>15</td>
<td>8</td>
<td>23</td>
</tr>
<tr>
<td>Continuation Review</td>
<td>12</td>
<td>0</td>
<td>12</td>
</tr>
<tr>
<td>Modification Review</td>
<td>10</td>
<td>2</td>
<td>12</td>
</tr>
<tr>
<td>Exempt Protocols</td>
<td>41</td>
<td>73</td>
<td>114</td>
</tr>
<tr>
<td>Incomplete</td>
<td>5</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>Not HSR</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Rejected</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>86</strong></td>
<td><strong>86</strong></td>
<td><strong>172</strong></td>
</tr>
</tbody>
</table>

161 of the 172 protocols submitted to the IRB were approved. Eight (8) of the remaining protocols required additional information for review. The information was requested but had not been received at the time of this report. The IRB required modifications to one of the protocols to gain approval, although, in addition, the chair worked with many investigators during the review process to eliminate the need for modifications later. Two of the protocols submitted were found not to be considered human subjects research. Such research does not require the approval of the IRB. One protocol was rejected because the research had already begun prior to application for approval. The chair worked with the researcher in order to produce a new research protocol which met federal regulations. That protocol was approved.
Compared to last year, the number of faculty-initiated protocols increased from 63 to 86 (+36%) and the number of student-initiated protocols decreased from 96 to 86 (-10%). The total number of submitted protocols increased from 159 to 172 (+8%).

Note that the Department of Teacher Education submits all their students’ master’s theses projects for Board approval. Two cohorts of Teacher Education students account for 64 of the above student-initiated protocols.

3) The current membership of the Board with terms of appointment indicated.

The board is made up of eleven (11) members and an equal number of alternates. Both members and alternates participate equally in reviewing protocols. A distinction is only made during full board meetings as required by federal regulation.

Members:

1. Kevin Brown, Chair, Math and Computer Science  Term Ends: Fall 2012
2. Lois Ritter, Nursing and Health Sciences  Term Ends: Fall 2011
3. Catherine Coulman, Student Health Services  Term Ends: Ex-officio
4. Ann Halvorsen, Educational Psychology  Term Ends: Fall 2012
5. Diana Wakimoto, Chair, Committee on Research  Term Ends: Ex-officio
6. Rhea Williamson, ORSP  Term Ends: Ex-officio
7. Nidhi Mahendra, Communicative Sciences and Disorders  Term Ends: Fall 2012
8. Nancy Dommes, Community Representative  Term Ends: Fall 2011
9. Janet Patterson, Communicative Sciences and Disorders  Term Ends: Fall 2011
10. Zinovy Radovilsky, Management and Finance  Term Ends: Fall 2012
11. David Sandberg, Psychology  Term Ends: Fall 2011

Alternates:

1. Catherine Calson, Community Representative  Term Ends: Fall 2012
2. Susan Rodearmal, Kinesiology & Physical Education  Term Ends: Fall 2011
3. Michael Hedrick, Biological Sciences  Term Ends: Fall 2011
4. Valerie Helgren-Lempesis, Teacher Education  Term Ends: Fall 2011
5. Kimberly Kim, Nursing and Health Sciences  Term Ends: Fall 2010
6. Marvin Lamb, Psychology  Term Ends: Fall 2012
7. Robert Peppard, Communicative Sciences and Disorders  Term Ends: Fall 2012
8. Phu Phan, Social Work  Term Ends: Fall 2010
9. Terry Soo-Hoo, Educational Psychology  Term Ends: Fall 2012
10. Jessica Weiss, History  Term Ends: Fall 2012
11. Evaon Wong-Kim, Social Work  Term Ends: Fall 2011

4) A citation of current, relevant legislation and regulatory requirements which govern the actions of the IRB.

5) Notes on developments at the national, state, local community and university levels that may require policy revisions to provide assurance as defined by Federal regulations, changes, or addenda or other administrative attention or action.

The board instituted a training policy for investigators conducting research using human subjects which was approved by the Academic Senate on June 3, 2008. The training program was implemented by subscribing to the CITI Human Subjects Research Training program, an online training program hosted by the University of Miami. Compliance with the training requirement was required for investigators submitting protocols and all IRB members from Spring quarter 2009 onward. The ORSP maintains a database of investigators who have completed the training. During the time covered by this report, 191 faculty, staff, and student investigators had completed the training.

6) Recommendations for administrative or Academic Senate actions for maintaining an effective institutional review function for the purpose of protecting the rights and welfare of human subjects.

None at this time.

Respectfully submitted,

Kevin Brown  
Chair, Institutional Review Board